
From: Katie Eberspacher[/O=SAFE CHAIN/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=2CA4D30C74894BEABE2BDC42911F9464-KATIE E]
Sent: Thur 7/5/2018 7:00:03 PM (UTC)
To: Charles Boyd[CharlesB@Safechain.com]; Pat Boyd[PatB@Safechain.com]
Subject: VAWD newsletter
Attachment: wholesale-drug-distribution-protecting-the-integrity-of-the-nations-prescription-drug-supply.pdf

Even though this article is from 2013 it's an interesting read to see how the NABP portrays "gray" wholesale distributors. If our lawyers and AIPW are not already aware of this article we may want to pass it along to them since the NABP uses a lot of derogatory terms to describe secondary distributors which would lead entities like Optum Rx or a specialty pharmacy to question our practices often times leaving us "disqualified". They use terms like schemes, exploitation and rogue wholesale distributors. Not sure if this is ammo we can use but worth a shot.

"Exploiting the loopholes in the system, potentially rogue wholesale distributors have found ways to justify their suspect actions. Utilizing current rules as a defense, these wholesalers have manipulated their way into the distribution system through various means, the top four most exploited of which include hiding behind the "five percent rule," abusing the emergency transfer exemption to wholesale distribution, operating under the pretense of an intracompany transfer, and virtual wholesalers." Page 5

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Wholesale Drug Distribution: Protecting the Integrity of the Nation's Prescription Drug Supply

National Association of Boards of Pharmacy

August 2013

The National Association of Boards of Pharmacy® (NABP®) is the independent, international, and impartial Association that assists its member boards and jurisdictions in developing, implementing, and enforcing uniform standards for the purpose of protecting the public health.

In keeping with this mission, NABP seeks to address the ongoing threat of counterfeit medications entering the nation's drug supply chain – a continued concern dating back to the 1980s when the United States experienced an initial flood of counterfeit drug products entering the United States.¹ This threat to patient safety and the

What is Wholesale Distribution?

Wholesale distribution is the distribution of prescription drugs or devices by wholesale distributors to persons other than consumers or patients.

realization 25 years ago that insufficient safeguards were in place to protect the prescription drug distribution system spurred Congress into action. However, a pattern of proposals and delays has ensued since those initial actions, leaving the integrity of the nation's prescription drug supply at continued risk.

An Overview of the Problem

A flawed wholesale drug distribution system and the availability of diverted and counterfeit prescription drugs are a very dangerous combination for the American public. Over the last year or so, the country has experienced supply chain incursions of significant proportions. Consider the impact of two massive prescription drug diversion investigations totaling over \$1 billion in fraud that were announced in 2012. The scope of these investigations is unparalleled. The counterfeit Avastin® and Altuzan® incidents also point to the roles of licensed wholesalers in distributing counterfeit drugs and unapproved foreign-sourced oncology drugs. It should be expected that unless states and Food and Drug Administration (FDA) are appropriated additional resources, supply chain events such as these will only get worse, increasing in frequency and scope in the coming months and years. The current regulatory environment is tilted in the favor of criminal organizations, prescription drug diverters, and corrupt supply chain participants. Failing to address the supply chain vulnerabilities that contributed to these events will ensure their continuation and this does not bode well for the American public. New approaches and resolute leadership are desperately needed to reverse this trend and create positive momentum toward developing a stronger and safer wholesale drug distribution system.

¹Two high profile cases, in particular, spurred congressional action – over 2 million unapproved Ovulen-21 birth control tablets and counterfeit versions of the antibiotic Ceclor®. “Counterfeit Drugs.” Statement of Randall W. Lutter, PhD, acting associate commissioner of policy and planning, FDA, before the Subcommittee on Criminal Justice, Drug Policy, and Human Resources House Committee on Government Reform. www.fda.gov/newsevents/testimony/ucm112670.htm. Accessed October 17, 2012.

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The Current Threat

The most prolific counterfeiting incident that occurred over the last 10 years involved Lipitor[®] in 2005. In that case, three businesses and 11 individuals were charged in connection with a \$42 million dollar conspiracy that involved the distribution of counterfeit Lipitor manufactured in Costa Rica and misbranded Lipitor smuggled into the US from South America, as well as for distributing stolen drugs. As a result of this case, a massive and unprecedented recall of 18 million Lipitor tablets was initiated by one of the distributors. This case highlighted how corrupt wholesale drug distributors played key roles in facilitating the distribution of counterfeit, diverted, and stolen drugs into the legitimate supply chain.

Fast forward to 2012 when two federal prescription drug diversion investigations totaling more than \$1 billion dollars in fraud were announced. In July 2012, federal criminal charges were filed against 48 individuals involved in the diversion of drugs that were originally dispensed to Medicaid patients and later resold back to pharmacies through corrupt wholesalers, resulting in over \$500 million dollars in fraudulent Medicaid reimbursements. In the second case conducted by FDA's Office of Criminal Investigations, 23 individuals and three corporations were charged in connection with a prescription drug diversion scheme spanning multiple states and totaling more than \$600 million dollars in fraud. According to the Department of Justice press release, from 2007 until 2011, the defendants supplied diverted drugs to chain and independent pharmacies all over the country. None of the drugs these diverters sold originated from authorized distributors as was claimed on the pedigrees. Assistant US Attorney Rosa Emilia Rodríguez-Vélez commented, "pharmacies received drugs of unknown quality and origin whose false pedigrees made it practically impossible to trace or determine the true source of the drugs."

As these two recent criminal cases illustrate, the prescription drug diversion problem has increased dramatically since 2005, but state and federal regulators have not been able to keep pace. Beginning in February 2012, FDA issued the first of several public statements regarding counterfeit versions of Avastin and Altuzan that may have been purchased by medical professionals throughout the country. A licensed wholesale drug distributor in Tennessee, Volunteer Distribution, was identified as being a distributor of foreign-sourced unapproved oncology drug products sold to medical professionals, and possibly the counterfeit Avastin as well. Almost one year later, FDA alerted medical professionals about a counterfeit version of Altuzan that was distributed by yet another licensed wholesale drug distributor, Pharmalogical, located in New York. It is unknown whether these two distributors conducted any legitimate transactions involving FDA-approved drug products, or if their businesses were comprised of nothing but illegal foreign-sourced unapproved oncology medications.

The counterfeit Avastin and Altuzan incidents underscore that the wholesale drug distribution system remains vulnerable to persons willing to commit unconscionable acts affecting seriously ill patients. Until we impose more robust oversight to prevent corrupt wholesalers from doing business, the supply chain and patients everywhere remain exposed to the very real dangers of counterfeit drugs, foreign unapproved drugs, and diverted drugs. The very real possibility that the supply chain is riddled with corrupt wholesalers like these is unsettling. A sense of urgency is needed among state and federal authorities responsible for supply chain security. These bad actors must be rooted out, or it can be expected that patients will continue to be at risk.

Wholesale Drug Distribution: Protecting the Integrity of the Nation's Prescription Drug Supply**Establishing Wholesale Distribution Regulation**

On April 12, 1988, President Ronald Reagan signed into law the Prescription Drug Marketing Act of 1987 (PDMA), setting the baseline for wholesale distribution regulations. The final regulations were published in 1999, establishing the minimum wholesale distribution requirements for state licensure.

With the intent to prevent the introduction and retail sale of substandard, ineffective, or counterfeit drugs

Provision of the Prescription Drug Marketing Act of 1987:

- Minimum required information for licensure of wholesale distributors of prescription drugs.
- Minimum qualifications; specifications on personnel.
- Violations and penalties.
- Minimum requirements for the storage and handling of prescription drugs and for the establishment and maintenance of prescription drug distribution records.

into the distribution system, state licensing systems moved to update their standards to match those provided federally as guided under FDA's Guidelines for State Licensing of Wholesale Prescription Drug Distributors (21 CFR 205). Though this movement by the states had a positive impact on the regulation of primary wholesale distributors, this state-by-state implementation resulted in a patchwork of minute regulations, leaving many states vulnerable to gray market entry into the their drug distribution system. Fifteen years after the signing of the PDMA, an influx of counterfeit medications reentered the supply chain, leading to a scramble on both the state side and federally to implement stricter regulations.

Post PDMA Era, Initialization of VAWD

The reappearance of counterfeit drugs in the supply chain in the early 2000s called to attention the existing holes in the regulatory system despite federal and state attempts to maintain the integrity of the drug distribution system. In addition, the federal drug pedigree requirement initially included in the PDMA as modified by the Prescription Drug Amendments of 1992 was delayed after meeting resistance and concerns from the industry, industry associations, and members of Congress early on.² The states sought ways to protect the prescription drug supply by increasing licensing requirements, developing their own pedigree requirements, recognizing or requiring accreditation by a qualified entity, and increasing criminal penalties to dissuade suspect wholesale distributors from entering the distribution system

Pedigrees

Drafting pedigree rules modeled from those included in the initial PDMA, several states proceeded with more stringent pedigree requirements. As with the general standards for wholesale distribution, however, many of the states' pedigree laws were in need of more stringent requirements and unknowingly created additional regulatory loopholes across the nation.

A few states, however, did take steps to develop firmer laws. With paper pedigree requirements in place as early as 1991, in 2001, Nevada mandated an extensive wholesale distributor licensure application and

Even with pedigree requirements in place, suspect wholesale distributors have found ways around the system by falsifying their drug pedigrees.

² The pedigree requirement was to require each person engaged in the wholesale distribution of a prescription drug in interstate commerce, who is not the manufacturer or an authorized distributor of record for that drug, to provide a pedigree to the recipient. After meeting resistance from various stakeholders, FDA delayed the effective date of the regulations several times, until final implementation in December 2006. *Federal Register*: www.gpo.gov/fdsys/pkg/FR-2006-11-15/pdf/06-9211.pdf.³ *Shining Light on the Gray Market – An Examination of Why Hospitals Are Forced to Pay Exorbitant Prices for Prescription Drugs Facing Critical Shortages*. Published July 25, 2012. Congressional Report from Ranking Member of the House Committee on Oversight and Government Reform Elijah E. Cummings.

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criminal background check process. Additionally, Florida reinforced its pedigree requirements to require pedigrees for **all** distributions of prescription drugs back to the manufacturer and in 2003, became the first state to allow and recognize electronic pedigrees. Nevada also began to allow e-pedigrees in 2007, and in California a drug pedigree law will soon require serialization, e-pedigrees, and track and trace systems. California's law will be implemented on a graduated schedule from 2015 through 2017.

VAWD

In addition to state adoption of pedigree requirements, many began to look to NABP's Model Rules for the Licensure of Wholesale Distributors for guidance by further increasing their licensing requirements to incorporate an accreditation component into their regulations, such as the NABP Verified-Accredited Wholesale Distributors[®] (VAWD[®]) program.

NABP is the only entity that regularly inspects and investigates wholesale distributors.

In 2004, NABP established VAWD after a request from FDA for NABP to update its Model Rules, as part of the *Model State Pharmacy Act and Model Rules of the National Association of Boards of Pharmacy (Model Act)*.

VAWD-accredited wholesale distributors undergo a criteria compliance review, including a rigorous review of their operating policies and procedures, licensure verification, on-site survey of facility and operations, background checks, and screening through the NABP Clearinghouse.

Recently, to further protect the integrity of the US drug supply chain, NABP updated the VAWD criteria to provide a more pronounced definition of

responsible distribution practices necessary to address the influx of VAWD applicants with indeterminate supply chains in addition to providing assurance that drugs diverted from pharmacies and unlawful sources are prevented from entering into the supply chain. The criteria were also revised to allow for virtual manufacturers and virtual wholesalers to qualify for VAWD.

Currently, 21 states recognize VAWD. Furthermore, VAWD accreditation, or certification by another accredited body approved by the board, is specifically required in Indiana, Maryland, North Dakota, and Wyoming. Additionally, some states, such as Maine, require VAWD as a condition of license renewal for disciplinary cases. NABP has also witnessed a more recent trend in hospitals, insurance entities, and other health care entities and buying groups requiring their wholesalers to be accredited through VAWD as a way to protect members from questionable entities offering short supply drugs. In light of this information, NABP is continuing to assess and strengthen VAWD to ensure that corrupt distributors do not obtain accreditation as a means to gain a competitive edge in the marketplace and abuse the trusted VAWD Seal to engage in diversion activities.

Wholesale Distribution Today – Pedigrees, VAWD, and Beyond

Suspect Wholesale Distributors Profiteer the System

The movement for states to implement more stringent wholesale distribution regulations does not appear to have halted suspect wholesalers from endangering the nation's supply chain. Instead, these questionable entities have managed to identify the gaps in the distribution and regulatory structure in order to swindle their way into the drug distribution system.

Scoping Out State Laws

In some cases, these profiteers specifically seek out states where requirements for licensure are less stringent. These problematic wholesale distributors have been known to pursue licensure in states where:

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- pedigrees are not required by the state
- licensure of out-of-state wholesale distributors is either optional or not required at all
- businesses are able to register for one wholesale distribution license and use the same license across the country for several entities
- there is a lack of inspection requirements for wholesale distributors (either by the state of domicile or by a third-party entity such as VAWD)
- the wholesale distribution laws are not strictly enforced

With pre-attained knowledge of states where regulations are not strictly enforced, suspect wholesale distributors often obtain licensure in these states to gain entry into a vulnerable distribution system.

Justifying Questionable Actions

Exploiting the loopholes in the system, potentially rogue wholesale distributors have found ways to justify their suspect actions. Utilizing current rules as a defense, these wholesalers have manipulated their way into the distribution system through various means, the top four most exploited of which include hiding behind the “five percent rule,” abusing the emergency transfer exemption to wholesale distribution, operating under the pretense of an intracompany transfer, and virtual wholesalers.

1. **Hiding Behind the “Five Percent Rule”:** Pharmacies acting as wholesalers have been found to take advantage of the parameters set by some states when it comes to drug distribution. Rather than dispensing the drugs as mandated, these pharmacies retain them to resell to wholesalers at an amount exceeding the specified quantity of prescription medications as permitted in certain states (often times 5% of annual sales). Some have gone as far as to sell their entire inventory into the gray market.³
2. **Emergency Transfer Exemption:** Pharmacies sell drugs to wholesale distributors under the guise of a medical emergency transfer in order to obtain exemption from the definition of a wholesale distributor.
3. **Intracompany Transfer:** Companies disguise their transactions as transfers between related companies under common ownership and control by a corporate entity when they are, in fact, not. This allows the potentially “fake” pharmacy to transfer drugs directly to the wholesaler.
4. **Virtual Wholesalers:** An emerging sector in drug supply chain, virtual wholesale distribution often time takes place without the virtual wholesale distributor taking physical possession of the drug. The products may then pass through several steps in the process before reaching their final destination, leaving them vulnerable to counterfeiting or unregulated conditions.

The “Five Percent Rule”

Though not specifically referenced federally as the five percent rule, FDA exempts a pharmacy from having to register as a wholesaler if the sale of the drug by the retail pharmacy is of “minimal quantities” and is to a licensed practitioner for office use. In the preamble to this rule, however, FDA further states its intended interpretation of “minimal quantities” as not exceeding 5% of the dollar volume of the pharmacy’s annual prescription drug sales. Many states have chosen to adopt this exemption based on the stated interpretation, allowing for pharmacies to distribute to other pharmacies and to practitioners.

³*Shining Light on the Gray Market – An Examination of Why Hospitals Are Forced to Pay Exorbitant Prices for Prescription Drugs Facing Critical Shortages*. Published July 25, 2012. Congressional Report from Ranking Member of the House Committee on Oversight and Government Reform Elijah E. Cummings.

Wholesale Drug Distribution: Protecting the Integrity of the Nation's Prescription Drug Supply***Current Schemes***

With the current drug shortages and frequent exploitation of the three aforementioned wholesale distributor justifications, the vulnerability of the distribution system remains exposed, leaving an open window for suspect wholesalers to engage in diversion related activities. Hiding under the pretext of providing aid, some wholesalers have gone as far as to contact hospitals directly to gather lists of drugs in short supply with a hidden agenda. These rogue entities then proceed with purchasing the entire supply of the much needed medications from pharmacies, allowing them to increase the cost prior to selling the drugs to the hospitals. Oftentimes, this act of hoarding by the unscrupulous entity leads to unused and wasted medications.

Additionally, entities have found ways to take advantage of the distribution system through schemes used to transfer drugs directly from pharmacies to wholesalers under the guise of an intracompany transfer. Ploys to disguise such actions can include:

- Wholesaler owns the pharmacy from which all drugs are transferred prior to being sold to the hospital.
- A pharmacy and wholesaler have the same owner but are based in two different locations
- A pharmacy and wholesaler have two different names but are located at the same physical address.
- A wholesale license is issued to a wholesaler with the same name and address as a pharmacy

Common Suspect Wholesale Distributor Schemes:

- Seeking out states with less stringent laws.
- Justification by hiding behind the five percent rule or emergency transfer exemption.
- Seeking out short supply drugs, hoarding them, and selling them at exorbitant costs.
- Using the same name, address, or both for a pharmacy and a wholesaler in order to act under the guise of an intracompany transfer.

In these instances, especially when a pharmacy has the same name and/or address as the licensed wholesaler, issues arise in the audit trail making it almost impossible to distinguish between the two. This problematic scheme, though not the intent of the rule or the interpretation, is even allowed in some states' regulations. Since it is not specifically written in the rule that a pharmacy cannot transfer directly to a wholesaler, suspect entities manipulate the interpretation, often further exacerbating the drug shortage.

NABP addressed these concerns during the December 2012 Task Force on Virtual Manufacturers and Virtual Wholesale Distributors. The task force recommended revisions to the VAWD criteria that would require pharmacies and distributors that are co-located to demonstrate that they have: (1) systems in place to separate and secure each entity's drugs; and (2) an audit trail that clearly identifies each entity's purchases and sales. Likewise, the task force agreed to add a provision to the Record Keeping section of the criteria to require this clear audit trail in order to prevent interchanging purchases or sales by a wholesale distributor that is located at the same address and with the same name as a pharmacy, physician, or other health care entity.

Exploiting the Drug Shortage

With the growing number of prescription drug shortages in the US, particularly injectable drugs used in hospitals to treat patients with cancer and other serious illnesses, "gray market" companies are taking advantage of the situation, charging 1,000 times, or more, the normal drug price. This widespread practice has resulted in "fake" pharmacies acquiring drugs from distributors and selling the high demand drugs into the gray market, in addition to drug brokers recruiting pharmacies to purchase drugs for the gray market. Rather than traveling through the normal distribution chain, medications will often circulate through the hands of several different secondary wholesalers before making their way to the hospital

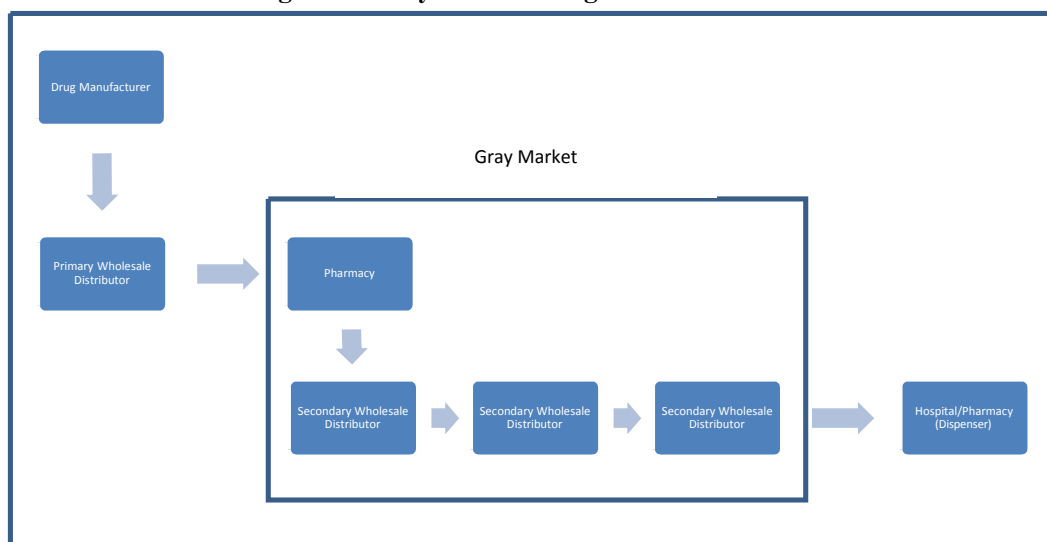
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where the drug will be sold at an exorbitant cost.⁴ (See Figures 1 and 2 for samples of a typical drug distribution model and a gray market drug distribution model.)

Figure 1: Typical Drug Distribution Model



Figure 2: Gray Market Drug Distribution Model



In addition to these gray market concerns, issues have been identified for drugs purchased within the closed distribution system. Common occurrences include counterfeiting; stolen or improperly stored drugs; recycling of previously dispensed medications such as those dispensed through Medicaid; sample shucking; reintroduction of drugs sent for destruction; and drugs sold for export, government contracts, 340B eligible entities, or under group purchasing organization contracts – such as closed pharmacies for long-term care and infusion pharmacies for home care. These are some of the most serious forms or diversion that have the greatest risk to patient safety. Perhaps more emphasis should be placed on diversion schemes related to Medicaid fraud/foreign unapproved drugs. In fact, FDA referred to the problem of foreign sourced unapproved oncology drugs as an epidemic of unapproved and counterfeit drugs.

⁴ *Shining Light on the Gray Market – An Examination of Why Hospitals Are Forced to Pay Exorbitant Prices for Prescription Drugs Facing Critical Shortages*. Published July 25, 2012. Congressional Report from Ranking Member of the House Committee on Oversight and Government Reform Elijah E. Cummings.

Wholesale Drug Distribution: Protecting the Integrity of the Nation's Prescription Drug Supply***Virtual Manufacturers and Distributors***

With the ever increasing incorporation of technology into the pharmacy industry, virtual manufacturing and distribution in the drug distribution system have become a common practice. Unlike the traditional route of drug manufacturing and distribution, in virtual instances a manufacturer maintains ownership of the drug product, including all intellectual property, but does not take physical possession of the product as it may be sent to a packager, then a third-party logistics provider, and then shipped. As with the circulation of drugs in a gray market environment, in virtual distribution the product may pass through several steps before reaching its final destination. Drug brokers acting as virtual wholesalers may also be involved in the process and act under similar circumstances to virtual manufacturers with the broker acquiring ownership of the finished drug product, but never possessing the product. The vast number of steps and entities involved in this process can often leave the drug products vulnerable to counterfeiting or unregulated conditions as the audit trail for these drugs becomes more complicated to monitor. This leaves concern for compliance with storage requirements as the lack of oversight in any one of the many steps in this distribution process can make it impossible to guarantee that the product is still usable by the time it reaches the final destination. These types of manufacturing and distribution models are inherently more risky and increased oversight is necessary to ensure these supply chain participants are held to the same standards as their more traditional counterparts.

In response to these concerns and as directed by Resolution No. 108-2-12 passed during the NABP 108th Annual Meeting, the previously mentioned December 2012 Task Force on Virtual Manufacturers and Virtual Wholesale Distributors reviewed the *Model Act* and VAWD criteria to ensure that virtual wholesale distribution and manufacturing were properly addressed. The VAWD criteria now allows virtual manufacturers and virtual wholesale distributors to qualify for VAWD accreditation.

What's Next? How Do We Eliminate the Holes in the Distribution System?***State Regulations***

From a regulatory perspective, it is up to the states to implement and enforce new or more stringent laws to close the gaps in the currently vulnerable distribution system. One key aspect where states may direct their focus is on the licensure and inspection requirements geared toward out-of-state wholesale distributors. With laws and regulations varying from state to state, licensing an out-of-state wholesale distributor can prove arduous; however, states can take action to eliminate unscrupulous wholesalers looking for loopholes in the regulatory system by ensuring that all out-of-state applicants seeking licensure are held to the same regulations in their state of domicile, if not more stringent. The states may be able to close some of the gaps caused by a lack of standard regulations across the nation. As previously mentioned, though these types of requirements may already be in place in several states, it is well known among the wholesale distributor community which states do not strictly enforce them. To further secure the supply chain and drug distribution system at the state level, the NABP Model Rules and VAWD program can assist in standardization of the overall regulations by providing common language and requirements for the states to utilize.

Adopting risk-based strategies to identify and target corrupt wholesalers that are most likely to be engaging in diversion related activities is a way to weed out the bad actors before a tragic supply chain event occurs. Further, more attention can be paid to wholesale drug distributor license applications to ensure that licenses are not issued to drug diverters in the first place. Federal regulations give authority to deny licenses if granting one is determined not to be in the public interest.

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Additionally, to specifically address the aforementioned exploitation of the five percent rule and abuse of the emergency transfer exemption, the NABP membership adopted Resolution No. 109-2-13 during the NABP 109th Annual Meeting. The resolution urges the member boards of pharmacy to revise their five percent rules to only allow the transfer, distribution, or sale of prescription drugs between pharmacies, or from pharmacies to practitioners, for the purpose of dispensing or administering, but not for resale, and also recommends that the states prohibit the transfer, distribution, or sale of prescription drugs from pharmacies to wholesalers for resale. The resolution also urges the member boards to allow for the pharmacy transfer of medications only for emergency medical reasons, including a public health emergency declaration by federal or state officials and individual patient needs.

Federal Outlook

Federally, there have been discussions to raise the floor of the PDMA to mandate that the minimum licensure standards for wholesale distributors be raised at least to the level of the VAWD criteria. The addition of United States Pharmacopeia Chapter <1083> Good Distribution Practices – Supply Chain Integrity, to the United States Pharmacopeia and The National Formulary has also been proposed at a national level to create a new general information chapter as part of the series of information chapters describing the various aspects of the pharmaceutical supply chain. Mandated pedigree requirements remain minimal at the federal level (though the federal requirement for a pedigree still remains and it is a criminal offense not to issue one or to provide a false one); however, legislation was drafted to amend the PDMA to specify a requirement for a non-serialized pallet or lot level of track and trace. Known as RxTEC, if passed, this legislation would preempt state laws. Additionally, the Senate Health, Education, Labor, and Pensions (HELP) Committee is considering a draft proposal⁵ to improve drug distribution security by requiring more information be maintained as part of the transaction history and ensuring that the history goes back to the manufacturer as well some increases in the minimum licensing requirements for states that go beyond what was established in the PDMA. These improvements, however, do not sufficiently strengthen the supply chain and may create additional holes in the distribution system while preempting language in those states who have taken aggressive steps to increase their state licensing requirements. With the current minimal federal pedigree requirements, the onus remains with the states to tighten up their laws in order to protect the distribution system.

International Advancements

Outside of the US, several countries have taken action to implement pedigree and other tracking requirements in order to put a stop to the prevalence of counterfeits. Countries such as Argentina, Brazil, Nigeria, France, and Turkey have sought global solutions to halt suspect wholesalers from entering the drug distribution system.

Track and trace efforts in these countries allow manufacturers to send drug information to a central database where it can be accessed by all partners of the supply chain process. Any history relating to the drug is then available to the pharmacy.

Specifically, in Nigeria some drugs are dispensed in unit dosage with each container marked with a serial number. The patient is then able to use his or her cell phone to text the serial number directly to an authentication service to determine if a drug is genuine or fake.

Additionally, a national law in Turkey requires serialization of products. Though it is voluntary for pharmacists to include these serial numbers at the patient level, this process can provide data at a clinical

⁵US Senate Committee on Health, Education, Labor, and Pensions. Draft Proposal to Improve Drug Distribution Security. April 19, 2013: www.help.senate.gov/imo/media/TAM13064.pdf . Accessed June 19, 2013.

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level to determine patient compliance and usage in addition to identifying recipients of medications that have been recalled.

As seen with these international advancements, incorporation of technology into the distribution process has significant potential to further secure the supply chain. Though technology in the US is capable of supporting a standardized authentication element such as a radio-frequency identification tag, it has not yet been agreed upon as a national standardized approach. Currently, use of a two-dimensional data matrix is more commonly accepted as a label mechanism to track-and-trace product.

A report from the Institute of Medicine (IOM),⁶ *Countering the Problem of Falsified and Substandard Drugs*, however, recommends that FDA be authorized and funded to implement a track and trace system that would use technology such as barcodes to track drug products from manufacturer to patient. The report also indicates that cooperation among international pharmacy regulatory agencies and the tightening of the US drug distribution chain would help protect global public health from substandard and falsified drugs. In the report, IOM shares that “falsified or substandard drugs were sold in at least 124 countries in 2011.” The report recommends that the wholesale market in the US be restricted to distributors accredited by NABP's VAWD program, advising that this would not only improve the security of the US drug distribution chain, but also “build momentum for better controls” in developing countries. Additionally, IOM suggests that a voluntary international agreement could help to address substandard drugs in the global market by encouraging uniform regulatory and law enforcement systems.

Pedigrees Stateside

As previously mentioned, California is currently working toward implementation of its pedigree law. In 2004, California passed an electronic pedigree requirement in an attempt to reduce the prevalence of counterfeit drugs entering the supply chain. The requirement is set to take effect on a staggered basis from 2015 to 2017; however, if federal law addressing pedigree or serialization measures is enacted, California's law could be preempted. In a hearing entitled “Securing Our Nation's Prescription Drug Supply Chain,” held by the House Committee on Energy and Commerce, Subcommittee on Health,⁷ NABP provided testimony recommending the building of uniform and national standards – with the possible help of California's requirements – that all stakeholders would support. In addition, the Association stressed that the tracking and traceability of products be at the package level and made operational in 2015 and 2016 in order not to retreat on the current advances made by California and the timelines already committed to by a growing number of the industry.

In addition to the pedigree requirements, California will begin utilizing serialization at the unit level in order to distinguish one container of prescription drugs from another and to access pedigrees for each individual container. This process will allow regulators to determine the origin of the container and will assist in identifying if a product has been tampered with or is counterfeit. Likewise, NABP also noted in its testimony to the House Committee that a process should be established for the routine and regular verification of serial numbers.

⁶Institute of Medicine, *Countering the Problem of Falsified and Substandard Drugs*; February 2013. Report Brief:

[www.iom.edu/-/media/Files/Report%20Files/2013/Substandard_and-Falsified-](http://www.iom.edu/-/media/Files/Report%20Files/2013/Substandard_and-Falsified-Drugs/CounteringtheProblemofFalsifiedandSubstandardDrugs_RB.pdf)

[Drugs/CounteringtheProblemofFalsifiedandSubstandardDrugs_RB.pdf](http://www.iom.edu/-/media/Files/Report%20Files/2013/Substandard_and-Falsified-Drugs/CounteringtheProblemofFalsifiedandSubstandardDrugs_RB.pdf). Accessed June 19, 2013. Full Report:

[www.iom.edu/Reports/2013/Countering -the-Problem-of-Falsified-and-Substandard-Drugs.aspx](http://www.iom.edu/Reports/2013/Countering-the-Problem-of-Falsified-and-Substandard-Drugs.aspx). Accessed June 19, 2013.

⁷Catizone, Carmen. Testimony Before the Committee on Energy & Commerce, Subcommittee on Health, United States House of Representatives; April 25, 2013: <http://docs.house.gov/meetings/IF/IF14/20130425/100762/HHRG-113-IF14-Wstate-CatizoneC-20130425.pdf>. Accessed June 19, 2013.

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Conclusion

As suspect wholesalers continue to search for ways to enter into the drug distribution system, NABP will continue to seek out ways to close vulnerable gaps in the system and standardize the regulatory framework in an effort to assist the states in ensuring the security of the supply chain to further protect patients from counterfeit and substandard drugs. With the more recent proposed federal legislation to create a uniform national standard for drug pedigree, track and trace, and drug distributor licensing requirements, the potential to improve protection of the nation's prescription drug supply chain may prove monumental; however, with public safety a top priority, these standards must not negate advancements previously accomplished by the states and FDA to ensure the integrity of the supply chain. NABP supports uniform national standards, but cautions that these standards, in particular those relating to pedigrees, hold wholesale distributors to requirements no less than those set by California as well as by other states that may have more stringent requirements relating to wholesale distributors.